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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,260	02/13/2002	Domenica Simms	IVGN 261	6799

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EXAMINER	
BAUSCH, SARAH L	
ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/073,260	SIMMS ET AL.	
	Examiner	Art Unit	
	SARAE BAUSCH	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,16-18,21-25,27-31,55-57,61-63 and 66-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11, 16-18, 21-25, 27-31, 55-57, 61-63, 66-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/20/2008 has been entered.

2. Currently, claims 1-11,16-18,21-25,27-31,55-57,61-63 and 66-71 are pending in the instant application. Claim 12-15, 19-20, 26, 32-54, 58-60 and 64-65 have been canceled and claim 71 is new. This action is written in response to applicant's correspondence submitted 02/13/2002. All the amendments and arguments have been thoroughly reviewed but were found insufficient to place the instantly examined claims in condition for allowance. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This action is Non-Final.

Withdrawn Rejections

3. The rejections of claims 67-70 under 35 U.S.C. 112, first paragraph, made in section 4, page 2 of the previous office action mailed 05/19/2008, is withdrawn in view of the amendment to the claims.

4. The rejection of claims 1-11, 16-18, 21-25, 27-31, 55-57, 61-63, and 66 made in section 6 of the office action mailed 05/19/2008 is withdrawn in view of the amendment to the claims.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 67-71 is rejected under 35 U.S.C. 102(b) as being anticipated by Nieuwkerk et al. (US Patent 5438128). This rejection is previously presented and has been rewritten to address the newly added claim 71.

With regard to claim 67-70, Niewkerk et al. teaches Nieuwkerk et al. teaches a method for convenient and rapid isolation of nucleic acids (see column 2 lines 64-68) which comprises membranes stacked one on top of the other to form a column having a short bed depth (see column 5 lines 52-56) (multilayer filter bed comprising a first and second filter layer). Nieuwkirk et al. teaches a device for the isolation of nucleic acids that comprises stacked membranes that have a pore size of .1 to 12 microns (first filter layer is about .1 to 1.0 microns, .2 microns) (claims 68-69) and teaches that the preferred number of stacked membranes is from one to 20 (see column 2, lines 28-40). Niewkirk teaches that the stacked membranes provide a short bed length to allow the column to be used with low pressure systems, including a simple vacuum manifold and hand held syringe, as well as the short bed reduces the quantity of eluant required (see column 5 lines 60-65). Further Nieuwkirk teaches the device allows for a small easy to use disposable device (see column 5 lines 40-50). Nieuwkirk et al. teaches plasmid purification by contacting the filter with cell lysate (see example 1, column 8 lines 28-67) (claim

70). Additionally, Nieuwkirk teaches a pore size ranging from .1 to 12 microns, which encompasses filter in which a first filter layer comprises pore sizes sufficient to retard cellular debris and the second filter comprises pores sufficient to shear DNA molecules.

With regard to claim 71, Nieuwkerk et al. teaches a method for convenient and rapid isolation of nucleic acids (see column 2 lines 64-68). Nieuwkirk et al. teaches plasmid purification by contacting the filter with cell lysate (isolating biological macromolecules from cellular lysate) (see example 1, column 8 lines 28-67) (claim 70). Nieuwkirk et al. teaches the device for the isolation of nucleic acids comprises stacked membranes that have a pore size of .1 to 12 microns and teaches that the preferred number of stacked membranes (filtration apparatus assembled into a cartridge housing with a first filter on top of a second filter) is from one to 20 (see column 2, lines 28-40). Nieuwkirk teaches the membranes are secured by an insert (see figure 1A and 1B).

Response to Arguments

7. The response traverses the rejection on pages 12-13 of the response mailed 10/20/2008. The response asserts that while Nieuwkerk teaches stacked membranes Nieuwkerk teaches separation of cell debris prior to filtration using centrifugation and not separation of cell debris using a filter. However, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., separation of cell debris using a filter) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). It is noted that the claims do not require that the cell debris is separated by the filter. The claims

merely require that DNA molecules are isolated from cell lysates by contacting a filter with cell lysate. The claims further require that the filter comprises pores size sufficient to retard flow of cellular debris and particles, however the claim does not require that cellular debris and particles contact the filter. Thus, Niewkirk teaching isolation of nucleic acid by lysis of cells and contacting the filter with cell lysate that has been centrifuged anticipates the claimed invention. Furthermore, Niewkirk does teach the use of the stacked membranes for plasmid DNA isolation from crude bacterial cell lysate by removing cellular material that does not bind the membrane (see column 7 lines 7-24) as well as claims the invention that cellular lysate sample is added to the membranes (see claim 1 of Niewkirk). Thus, Niewkirk teaches, as well as specifically claims that cell lysate, including cell debris which would be included in a crude bacterial lysate, is added to the stacked membranes and eluted prior to purification of the DNA.

For these reasons, and the reasons made of record in the previous office actions, the rejection is maintained.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-11, 16-18, 21-25, 27-31, 55-57, 61-63, and 66 rejected under 35 U.S.C. 103(a) as being unpatentable over Jones (PCT WO95/02049) in view of Nieuwkerk et al. (US Patent 5438128). This rejection is newly presented.

Jones (WO95/02049) teaches a method of purifying DNA (biological macromolecule) from *E. coli* bacterial culture (biological sample) by passing the cells through a 1 μm filter followed by a 20μm filter (page 22, 1st full paragraph). Jones et al. teaches that the method can be used for genomic DNA (see page 4, 1st paragraph).

With regard to claim 2, Jones teaches the method of purifying nucleic acid from cells that comprises lysing a cell suspension to form a cell lysate containing nucleic acid and applying the cell lysate to a filter to remove unwanted cells and cell debris (page 2, 4th full paragraph).

With regard to claims 3-5, Jones teaches that any cell producing a target compound may be used in their invention. Jones defines a "cell" to encompass bacterial cells, cells from higher organisms for example blood cells, phage particles, and other cell types or organelles which contain the target compound and may require some form of lysis step to release it (page 3, 4th full paragraph). The cells are lysed prior to applying to the first filter (page 2, 4th full paragraph).

With regard to claims 6-11, Jones teaches that the target compound to be separated may comprise nucleic acid (instant claim 6), protein, or other desired compounds, in particular purifying recombinant proteins and antibodies (instant claim 7)(page 2, 2nd and 3rd paragraph).

Jones further teaches that RNA or DNA may be purified using this invention (page 5, 2nd paragraph) (instant claim 8-11).

With regard to claims 16-18, Jones teaches the use of two filter layers to purify DNA from bacterial cells, with the first filter having 1μm pore size and the second filter having 20 μm pore size (instant claims 16-18) (page 22, 1st full paragraph).

With regard to claims 21-25 and 27, Jones teaches the use of a first filter that retains unwanted cells and cell debris (instant claim 21), that is made of any material that can tolerate the reagents such as cellulose acetate (acetylated cellulose) (instant claim 24 and 25) and is no greater than 50 μm in pore size and no smaller than .2 μm (instant claim 22-23) (page 6, 1st full paragraph). Jones teaches that for a nucleic acid, the filter is typically glass or resin based and can bind the nucleic acid such as borosilicate glass (see page 6, 2nd paragraph) (claim 24). Jones teaches that the first filter is no greater than 50 μm in pore size and no smaller than .2 μm (see page 6, 1st paragraph) and the second filter is a 20 μm pore size (see page 22, 1st full paragraph) (instant claim 27).

With regard to claim 28 and 29, Jones teaches the method of a membrane filter that is placed inside the column (tube) (instant claim 29) and has a cylindrical shape (instant claim 28) (page 11, last paragraph, figure 1 and figure 2).

With regard to claims 30-31, Jones teaches the method of lysing a cell suspension to form a cell lysate, applying the cell lysate to a filter to remove unwanted cells and cell debris, contacting the filtered lysate with a solid phase matrix, separating the resultant filtered lysate from the matrix, and eluting the nucleic acid from the matrix (page 2, 4th full paragraph). Jones teaches the method of purifying plasmid DNA by using a filtration method of increasing pore

sizes of two filters using a 1 μm filter followed by a 20 μm filter and promoting the flow of lysate through the filters by positive pressure (page 22, 1st full paragraph).

With regard to claim 55-57 and 61-63, Jones teaches the method of lysing a cell suspension from *E. coli* (natural source) to form a cell lysate, applying the cell lysate to a filter to remove unwanted cells and cell debris, followed by contacting the filtered lysate with a solid phase matrix, separating the resultant filtered lysate from the matrix, and eluting the nucleic acid from the matrix (page 2, 4th full paragraph). Jones teaches the method of purifying plasmid DNA (instant claim 57) by the method of increasing the pore sizes of the filters (instant claim 55), by using a 1 μm cellulose acetate filter followed by a 20 μm PTFE filter (instant claim 61-62) and promoting the flow of lysate through the filters by positive pressure (instant claim 56) (page 22, 1st full paragraph and Table 1, page 21). Jones teaches that for a nucleic acid, the filter is typically glass or resin based and can bind the nucleic acid such as borosilicate glass (see page 6, 2nd paragraph) (claim 63).

With regard to claim 66, Jones et al. teaches two filters that have the inherently property of shearing genomic DNA, as evidenced by applicant's own specification (see page 13, last paragraph to page 14, 1st line).

Jones does not teach that the first and second filter layer is within the same hollow body or comprises a multilayer filter bed.

However, Nieuwkerk et al. teaches a method for convenient and rapid isolation of nucleic acids (see column 2 lines 64-68) which comprises membranes stacked one on top of the other to form a column having a short bed depth (see column 5 lines 52-56) (multilayer filter bed). Nieuwkirk et al. teaches a device for the isolation of nucleic acids that comprises stacked

membranes that have a pore size of .1 to 12 microns and teaches that the preferred number of stacked membranes (first and second filter directly contacting) is from one to 20 (see column 2, lines 28-40). Niewkirk teaches that the stacked membranes provide a short bed length to allow the column to be used with low pressure systems, including a simple vacuum manifold and hand held syringe, as well as the short bed reduces the quantity of eluant required (see column 5 lines 60-65). Further Nieuwkirk teaches the device allows for a small easy to use disposable device (see column 5 lines 40-50). Nieuwkirk et al. teaches plasmid purification by contacting the filter with cell lysate (see example 1, column 8 lines 28-67) (claim 70).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to improve the method of isolating nucleic acids from cell lysate by using the filter apparatus as taught by Jones et al. to include multiple layer filter bed of filters housed within the same column, as taught by Nieuwkirk, to improve the method by Jones et al. to allow for a simpler, easier to use and disposable column. The ordinary artisan would have been motivated to improve the method of isolating nucleic acid from cellular lysate with the filter taught by Jones to include the filters housed in one column to thereby produce a multilayer filter bed as taught by Nieuwkirk because Nieuwkirk teaches that stacked membranes in a column allows for reduced quantity of eluant and use with low pressure systems, as well as provides a small, easy to use disposable device. The ordinary artisan would have had a reasonable expectation of success that the method of nucleic acids from cellular lysate of Jones modified to house the filters in one unit to produce a multilayer filter bed in the same hollow body, as taught by Nieuwkirk because Nieuwkirk et al. teach that multilayer filters can be used to isolated nucleic acid from cellular debris (see example 1).

Conclusion

11. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAE BAUSCH whose telephone number is (571)272-2912. The examiner can normally be reached on M-F 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Sarae Bausch/
Primary Examiner, AU 1634